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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,423	10/12/2001	Kirk Hogan	HOGAN-06650	2436

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EXAMINER	
GOLDBERG, JEANINE ANNE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,423	HOGAN, KIRK	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-68 and 71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-68 and 71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☒ Other: 03-1524 (09/597,608)

DETAILED ACTION

1. This action is in response to the papers filed June 30, 2004. Currently, claims 45-68, 71 are pending.

2. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on June 30, 2004 has been entered.

3. This action contains new grounds of rejection.

Priority

4. This application claims priority as a continuation in part of 09/613,887, filed July 11, 2000.

Drawings

5. The drawings are approved by the examiner.

Maintained Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 45, 48-68, 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer Mannheim 1997 Biochemicals Catalog (page 95, Nucleic Acid Labeling and Detection).

It is noted that these claims contain a preamble which recites an intended use, however, it is also noted that this use does not confer patentable weight on the product claims since the preamble does not materially change what is present in the kit itself and thus represents an intended use of the kit (see MPEP 2111.02). Further, with regard to the limitation that the kits contain instructions for using said kit for generating said perioperative genomic profile for said subject, the inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a statement of intended use in the form of instructions in a kit. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004)(holding that an inventor could not patent known kits by simply attaching new set of instructions to that product).

Boehringer Mannheim provides several products which are packaged for distribution, kits, which detect the presence of variant alleles of two or more genes.

First, Boehringer Mannheim teaches Digoxigenin-3-O-methylcarbony-e-aminocaproic acid-N-hydroxy-succinimide ester which is suitable for 5'-end labeling of oligonucleotides. The label it thus capable of detecting the presence of variant alleles in hybridization assays using ASO probes, for example.

Second, Boehringer Mannheim teaches hybridization bags which can be used in non-radioactive hybridization and detection procedures, standard radioactive probe hybridizations and Western blotting procedures.

Third, Boehringer Mannheim teaches lumi-Film Chemiluminescent Detection film which is "ideal for detecting the signals from alkaline phosphatase chemiluminescent substrates in membrane hybridization techniques." These three products are only examples of a few of the products distributed by Boehringer Mannheim which are "reagents which detect the presence of variant alleles of two or more genes."

The claims also require "instructions for using said kit for generating said perioperative genomic profile for said subject." Because no patentable weight is given to the written material in the instructions describing a method, the claim is anticipated by Boehringer Mannheim Catalog. As decided at the Federal Circuit in May 2004, In re Ngai succinctly states that inventors are not "entitled to patent a known product by simply attaching a set of instructions to that product."

Therefore, since Boehringer Mannheim teaches every limitation of the claims, Boehringer Mannheim anticipates the claimed invention.

Response to Arguments

The response traverses the rejection. The response asserts that the prior art does not teach the specific variant allele elements of the present claims. This argument has been reviewed but is not convincing because the claims recite "reagents which detect the presence of variant alleles of two or more genes..." This limitation does not require any allele specific elements. Reagents which detect the presence of variant

alleles encompasses any product which may enable detection of variant alleles. The specification, nor the instant claims, limits reagents to be nucleic acid or more specifically, a nucleic acid flanking, or comprising a variant. As stated above, the instant claims require "reagents which detect the presence of variant alleles of two or more genes..." The claims does not include any recitation with respect to oligonucleotides or more specifically, no recitation of "ASO probes." Rather, the claim broadly encompasses ANY "reagents capable of detecting the presence of variant alleles of two or more genes..." Therefore, the Digoxigenin-3-O-methylcarbony-e-aminocaproic acid-N-hydroxy-succinimide ester which is suitable for 5'-end labeling of oligonucleotides, the hybridization bags which can be used in non-radioactive hybridization and detection procedures, standard radioactive probe hybridizations and Western blotting procedures; and the lumi-Film Chemiluminescent Detection film which is "ideal for detecting the signals from alkaline phosphatase chemiluminescent substrates in membrane hybridization techniques" each meet the limitation of the instant claims.

With response to the arguments directed to instructions, the response traverses the rejection (page 12, of response filed June 3, 2004. The response argues that "not one of the three prior art references recite the limitation 'instructions for using said kit for generating said perioperative genomic profile for said subject." This argument has been thoroughly reviewed, but is not found persusasive. The examiner previously addressed all of the instant arguments in the Final Office Action of July 8, 2003 and maintains these arguments. Additionally, in view of the recent Federal Circuit case holding that an

inventor could not patent known kits simply by attaching new sets of instructions to that product. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004). This is the precise issue argued at length by the instant response (pages 12-18). Since the facts and analysis of the instant application and Ngai are the same, Ngai is deemed the closest authority on the issue of whether printed instructions in a previously disclosed kit makes the kit patentable.

Moreover, the Declaration of Morris Waxler has been thoroughly considered and deemed not persuasive. The Declaration is specifically designed to establish that instructions for kits, for the purpose of FDA, are considered to be functional by the FDA. This argument has been thoroughly reviewed, but is not found persuasive because the standard to patentability does not rely on any requirements made by the FDA. As provided in MPEP 2107.01, for example, it is clear that the requirements for FDA and patent approval should not be confused. Thus, it is clear that the requirements for the FDA approval and for patent approval are not parallel and conclusions regarding FDA requirements are not persuasive or binding on the patent process.

With respect to the arguments (page 20-22) of the response filed on June 30, 2004, the response argues that "physically or chemically affect the chemical nature" and "uses for other purpose" is not the law. This argument has been thoroughly reviewed, but is not found persuasive because it is clear from the decision of Ngai that since the known products are not changed, the inventor can not patent known kits simply by attaching new set of instructions to that product."

With respect to Claim 71, the recitation "component parts which detect the presence of variant alleles" appears to be very similarly related to "reagents" of Claim 45. For the same reasons above, "component parts" has been interpreted very broadly to encompass any part which detects alleles.

Thus for the reasons above and those already of record, the rejection is maintained.

7. Claims 45, 48-68, 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Perkin Elmer, PCR Systems, Reagents & Consumables (1995-1996, pages 15-18).

It is noted that these claims contain a preamble which recites an intended use, however, it is also noted that this use does not confer patentable weight on the product claims since the preamble does not materially change what is present in the kit itself and thus represents an intended use of the kit (see MPEP 2111.02). Further, with regard to the limitation that the kits contain instructions for using said kit for generating said perioperative genomic profile for said subject, the inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a statement of intended use in the form of instructions in a kit. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004)(holding that an inventor could not patent known kits by simply attaching new set of instructions to that product).

Perkin Elmer provides several products which are packaged for distribution, kits, which allow for detecting the presence of variant alleles of two or more genes. First, Perkin Elmer teaches the GeneAmp PCR Reagent Kit with AmpliTaq DNA polymerase. The kit contains the components of AmpliTaq DNA polymerase, GeneAmp Buffer,

GeneAmp dNTPs, GeneAmp Lambda Control Reagents and package insert with PCR protocols (page 15). This kit provided by Perkin Elmer contains reagents which allow for detection of variant alleles of two or more genes. Perkin Elmer provides several additional variations of the PCR kit (page 16-18). Perkin Elmer specifically teaches that the kits can be used for a wide variety of research application including human genetics, environmental assay, genome mapping and analysis and the study of infections diseases (page 15).

The claims also require "instructions for using said kit for generating said perioperative genomic profile for said subject." Because no patentable weight is given to the written material in the instructions describing a method, the claim is anticipated by Perkin Elmer. As decided at the Federal Circuit in May 2004, In re Ngai succinctly states that inventors are not "entitled to patent a known product by simply attaching a set of instructions to that product."

Therefore, since Perkin Elmer teaches every limitation of the claims, Perkin Elmer anticipates the claimed invention.

Response to Arguments

The response traverses the rejection. The response asserts that the prior art does not teach the specific variant allele elements of the present claims. This argument has been reviewed but is not convincing because the claims recite "reagents which detect the presence of variant alleles of two or more genes..." This limitation does not require any allele specific elements. Reagents which detect the presence of variant alleles encompasses any product which may enable detection of variant alleles. The

specification, nor the instant claims, limits reagents to be nucleic acid or more specifically, a nucleic acid flanking, or comprising a variant. As stated above, the instant claims require "reagents which detect the presence of variant alleles of two or more genes..." The claims does not include any recitation with respect to oligonucleotides or more specifically, no recitation of "ASO probes." Rather, the claim broadly encompasses ANY "reagents capable of detecting the presence of variant alleles of two or more genes..." Therefore, the kit containing the components of AmpliTaq DNA polymerase, GeneAmp Buffer, GeneAmp dNTPs, GeneAmp Lambda Control Reagents and package insert with PCR protocols meets the limitation of the instant claims.

With response to the arguments directed to instructions, the response traverses the rejection (page 12, of response filed June 3, 2004. The response argues that "not one of the three prior art references recite the limitation 'instructions for using said kit for generating said perioperative genomic profile for said subject." This argument has been thoroughly reviewed, but is not found persuasive. The examiner previously addressed all of the instant arguments in the Final Office Action of July 8, 2003 and maintains these arguments. Additionally, in view of the recent Federal Circuit case holding that an inventor could not patent known kits simply by attaching new sets of instructions to that product. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004). This is the precise issue argued at length by the instant response (pages 12-18). Since the facts and analysis of the instant application and Ngai are the same, Ngai is deemed the

closest authority on the issue of whether printed instructions in a previously disclosed kit makes the kit patentable.

Moreover, the Declaration of Morris Waxler has been thoroughly considered and deemed not persuasive. The Declaration is specifically designed to establish that instructions for kits, for the purpose of FDA, are considered to be functional by the FDA. This argument has been thoroughly reviewed, but is not found persuasive because the standard to patentability does not rely on any requirements made by the FDA. As provided in MPEP 2107.01, for example, it is clear that the requirements for FDA and patent approval should not be confused. Thus, it is clear that the requirements for the FDA approval and for patent approval are not parallel and conclusions regarding FDA requirements are not persuasive or binding on the patent process.

With respect to the arguments (page 20-22) of the response filed on June 30, 2004, the response argues that "physically or chemically affect the chemical nature" and "uses for other purpose" is not the law. This argument has been thoroughly reviewed, but is not found persuasive because it is clear from the decision of Ngai that since the known products are not changed, the inventor can not patent known kits simply by attaching new set of instructions to that product."

With respect to Claim 71, the recitation "component parts which detect the presence of variant alleles" appears to be very similarly related to "reagents" of Claim 45. For the same reasons above, "component parts" has been interpreted very broadly to encompass any part which detects alleles.

Thus for the reasons above and those already of record, the rejection is maintained.

8. Claims 45-68, 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Applied Biosystems Product Catalog (1993, pages 135-164).

It is noted that these claims contain a preamble which recites an intended use, however, it is also noted that this use does not confer patentable weight on the product claims since the preamble does not materially change what is present in the kit itself and thus represents an intended use of the kit (see MPEP 2111.02). Further, with regard to the limitation that the kits contain instructions for using said kit for generating said perioperative genomic profile for said subject, the inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a statement of intended use in the form of instructions in a kit. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004)(holding that an inventor could not patent known kits by simply attaching new set of instructions to that product).

Applied Biosystems provides several products which are packaged for distribution, kits, which allow for detecting the presence of variant alleles of two or more genes. Applied Biosystems products for sale include: a DNA analysis system; software for genetic analysis; electrophoresis accessories including combs, alignment braces, glass plates, manuals; PRISM Ready reaction cycle sequencing kits; AmpliTaq Cycling Sequencing Kits; DNA sequencing Neat reagents Dye primers; activated dyes, template purification kits; etc. Each of these products is capable of detecting the presence of variant alleles of two or more genes. With respect to Claims 46-47, Applied Biosystems teaches numerous computer programs which are sold with the DNA analysis system, for example. This computer program, thus meets the limitations of Claim 46-47, as the

instructions on the computer program do not carry patentable weight, for the reasons discussed below for instructions.

The claims also require "instructions for using said kit for generating said perioperative genomic profile for said subject." Because no patentable weight is given to the written material in the instructions describing a method, the claim is anticipated by Applied Biosystems. As decided at the Federal Circuit in May 2004, In re Ngai succinctly states that inventors are not "entitled to patent a known product by simply attaching a set of instructions to that product."

Therefore, since Applied Biosystems teaches every limitation of the claims, Applied Biosystems anticipates the claimed invention.

Response to Arguments

The response traverses the rejection. The response asserts that the prior art does not teach the specific variant allele elements of the present claims. This argument has been reviewed but is not convincing because the claims recite "reagents which detect the presence of variant alleles of two or more genes..." This limitation does not require any allele specific elements. Reagents which detect the presence of variant alleles encompasses any product which may enable detection of variant alleles. The specification, nor the instant claims, limits reagents to be nucleic acid or more specifically, a nucleic acid flanking, or comprising a variant. As stated above, the instant claims require "reagents which detect the presence of variant alleles of two or more genes..." The claims does not include any recitation with respect to oligonucleotides or more specifically, no recitation of "ASO probes." Rather, the claim

broadly encompasses ANY "reagents capable of detecting the presence of variant alleles of two or more genes..." Therefore, the kit containing a DNA analysis system; software for genetic analysis; electrophoresis accessories including combs, alignment braces, glass plates, manuals; PRISM Ready reaction cycle sequencing kits; AmpliTaq Cycling Sequencing Kits; DNA sequencing Neat reagents Dye primers; activated dyes, template purification kits; etc.meets the limitation of the instant claims.

With response to the arguments directed to instructions, the response traverses the rejection (page 12, of response filed June 3, 2004. The response argues that "not one of the three prior art references recite the limitation 'instructions for using said kit for generating said perioperative genomic profile for said subject." This argument has been thoroughly reviewed, but is not found persuasive. The examiner previously addressed all of the instant arguments in the Final Office Action of July 8, 2003 and maintains these arguments. Additionally, in view of the recent Federal Circuit case holding that an inventor could not patent known kits simply by attaching new sets of instructions to that product. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004). This is the precise issue argued at length by the instant response (pages 12-18). Since the facts and analysis of the instant application and Ngai are the same, Ngai is deemed the closest authority on the issue of whether printed instructions in a previously disclosed kit makes the kit patentable.

Moreover, the Declaration of Morris Waxler has been thoroughly considered and deemed not persuasive. The Declaration is specifically designed to establish that instructions for kits, for the purpose of FDA, are considered to be functional by the FDA.

This argument has been thoroughly reviewed, but is not found persuasive because the standard to patentability does not rely on any requirements made by the FDA. As provided in MPEP 2107.01, for example, it is clear that the requirements for FDA and patent approval should not be confused. Thus, it is clear that the requirements for the FDA approval and for patent approval are not parallel and conclusions regarding FDA requirements are not persuasive or binding on the patent process.

With respect to the arguments (page 20-22) of the response filed on June 30, 2004, the response argues that "physically or chemically affect the chemical nature" and "uses for other purpose" is not the law. This argument has been thoroughly reviewed, but is not found persuasive because it is clear from the decision of Ngai that since the known products are not changed, the inventor can not patent known kits simply by attaching new set of instructions to that product."

With respect to Claim 71, the recitation "component parts which detect the presence of variant alleles" appears to be very similarly related to "reagents" of Claim 45. For the same reasons above, "component parts" has been interpreted very broadly to encompass any part which detects alleles.

Thus for the reasons above and those already of record, the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 45, 48-68, 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosen (US Publication 2002/0119468, August 2002) in view of Ahern (The Scientist, Vol 9, No. 15, page 20, July 1995).

Rosen teaches methods for identifying a preferred liver transplant donor. Rosen specifically, teaches the genotype of the tumor necrosis factor alpha and beta are analyzed. Rosen specifically takes liver biopsies from patients. Genomic DNA was isolated using a commercial extraction kit from Puregene DNA isolation Kit (a reagent which will detect the presence of variant alleles from two or more genes). Rosen teaches for the TNF-alpha promoter genotyping, a sample of DNA was amplified using PCR primers TNF3431 and TNF 4034 and then sequences using TNF3517 and TNF3966 using an automated sequencer (ABI377 Applied Biosystems). The primers are clearly reagents which allow for the detection of variant alleles, as the sequence configuration at the –308 and –238 positions of the TNF-alpha promoter was determined (para 61). Rosen specifically teaches detecting various alleles from TNF-alpha, either the G or A. Further Rosen teaches genotyping of selected loci of the TNF-alpha and TNF-beta coding regions was performed by PCR amplification and restriction digestion. Rosen teaches that TNF-beta aa13 and aa26 genotyping was performed using mutagenic primers that introduce a restriction enzyme half-site into the PCR product such that discrimination between the two alleles of the polymorph8ism can be tested with various restriction enzymes. Rosen provides analysis of both the TNF-alpha and beta genotypes and alleles.

Rosen does not specifically teaches packaging necessary reagents into a kit.

However, Ahern teaches reagent kits offer scientists good return on investment. Ahern teaches kits save time and money because the kits already comes prepared. Ahern teaches kits may comprise instructions that provide researcher detailed instructions to follow.

Therefore, it would have been **prima facie** obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Rosen with the teachings of Ahern to incorporate the necessary reagents into a packaged kit. Rosen specifically teaches two polymorphic genes which are associated with liver transplant donor. Based upon Table 1 and Table 2, the ordinary artisan would have been motivated to have sampled a liver donor for allele 1 in both TNF-alpha and TNF-beta to obtain a liver which is less likely to be rejected. The prior art teaches mutations at –308 and aa13 and aa26 which are associated with predisposition to liver rejection. Thus, the ordinary artisan would have been motivated to have packaged the primers, probes, and reagents of Rosen which are necessary for determining the genotypes of TNF-alpha and beta which are associated with liver donor rejection into a kit, as taught by Ahern for the express purpose of saving time and money.

10. Claims 45, 48-68, 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tarkowski et al. (Neurology, Vol. 54, pages 2077-2081, June 13, 2000) in view of Ahern (The Scientist, Vol 9, No. 15, page 20, July 1995).

Tarkowski et al. (herein referred to as Tarkowski) teaches TNF gene polymorphisms. Tarkowski teaches analyses of TNFalpha and TNFbeta gene polymorphism. The TNF alpha PCR was constructed and primer sequences were provided which allowed amplification, followed by subsequent digestion with NcoI to determine TNFalpha1 and TNFalpha2 alleles (-308G-A). The TNFbeta primers for amplification and then cleavage were also provided to distinguish the two alleles (+225G-A)(pages 2079). As seen in Figure 1 and 2, the alleles and frequencies in AD patients was provided.

Tarkowski does not specifically teaches packaging necessary reagents into a kit.

However, Ahern teaches reagent kits offer scientists good return on investment. Ahern teaches kits save time and money because the kits already comes prepared. Ahern teaches kits may comprise instructions that provide researcher detailed instructions to follow.

Therefore, it would have been **prima facie** obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Tarkowski with the teachings of Ahern to incorporate the necessary reagents into a packaged kit. Tarkowski specifically teaches two polymorphic genes which are associated with AD. Thus, the ordinary artisan would have been motivated to have packaged the primers, probes, and reagents of Tarkowski which are necessary for determining the genotypes of TNF-alpha and beta which are associated with AD rejection into a kit, as taught by Ahern for the express purpose of saving time and money.

Conclusion

11. No claims allowable over the art.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571) 272-0782.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeanine Goldberg
Patent Examiner
August 20, 2004